510(k) Notification

MAR 2 0 2007

Section E. Summary as required by section 807.92 (c)

Submitter: Licher Medizintechnologie GmbH
Marderweg 1
D-30900 Wedemark
Phone (01149) 5130 - 5855 - 30
FAX (01149) 5130 - 5855 - 40

Contact: Mr. Dieter Mushoff
C E O
Licher Medizintechnologie GmbH
Phone (01149) 5130 - 5855 - 30
FAX (01149) 5130 - 5855 - 40
Email lichermt@t-online.de

Date: 06 / 11 / 2006

Name of device LMT-KATH-S 28G 10mm x 60cm / 0,394" x 23,62"
LMT-KATH-S 28G 8mm x 60cm / 0,315" x 23,62"
LMT-KATH-I 25G 12mm x 60cm / 0,472" x 23,62"
LMT-KATH-I 25G 8mm x 60cm / 0, 315" x 23,62"

Common name: Subcutaneous Infusion Sets

Classification name of device: a) Product code: FPA
b) Regulation number: 880.5440

Predicate device: Disetronic Rapid and Rapid D Subcutanuous Infusion Sets

(Premarket Notification K003977)

Description of the sets:

Models no. 20500606 and 20500706

510(k) Notification

Section E. Summary as required by section 807.92 (c)

The LMT-KATH-S and LMT-KATH-I infusion sets are administration sets intended to deliver medications under the skin. Both connect at the female Luer to a reservoir, which, for example, can be delivered through the use of an external infusion pump or by medical injection. The stainless steel cannula is inserted into the subcutaneous tissue and fixed into place by an attached approximate circular disk bandage with medical grade adhesive. The tubing of both infusion sets is made of polyethylene.
The LMT-KATH-S and LMT-KATH-I infusion sets have identical components that allow the set to be disconnected/connected approximately 60 cm / 23.62" from the insertion site. The disconnect mechanism (Luer connector) on the reservoir side has a protector cap to maintain clean conditions during disconnection and to cover the connector. The tube may have additional bandages with medical adhesive grade.

Intended use of the Device:

LMT-KATH-S and LMT-KATH-I Infusion Sets are indicated for the infusion and/or injection of medication that is dispensed by means of micro-dosage pump into the body below the surface of the skin. These sets are intended to be used with manual injection and infusion and automated infusion with infusion pumps.

Comparison of the Technological Features of the New Device and Predicated Device:

The infusion sets "LMT-KATH-S" and "LMT-KATH-I" are substantially similar to the lawfully marketed predicated device. These sets are indicated for the infusion and/or injection of medication that is dispensed by means of micro-dosage pump into the body below the surface of the skin.

510(k) Notification
Section D.
Statement of Indications for Use

MAR 2 0 2007

Indications for Use Statement

510(k) Number: K062308

Device Name:
LMT-KATH-S 28G 10mm x 60cm / 0,394" x 23,62"
LMT-KATH-S 28G 8mm x 60cm / 0,315" x 23,62"
LMT-KATH-I 25G 12mm x 60cm / 0,472" x 23,62"
LMT-KATH-I 25G 8mm x 60cm / 0,315" x 23,62"

Indications for Use:
LMT-KATH-S 28G 10mm x 60cm / 0,394" x 23,62"
LMT-KATH-S 28G 8mm x 60cm / 0,315" x 23,62"
LMT-KATH-I 25G 12mm x 60cm / 0,472" x 23,62"
LMT-KATH-I 25G 8mm x 60cm / 0,315" x 23,62"
Infusion Sets are indicated for the infusion and/or injection of medication that is dispensed by means of micro-dosage pump into the body below the surface of the skin.

Prescription Use ____X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 0 2007

Mr. Dieter Mushoff
CEO
Licher Medizintechnologie GMBH
Marderweg 1
Wedemark, Germany D-30900

Re: K062308
Trade/Device Name: LMT-KATH-S 28G 10mm x 60cm; LMT-KATH –S 28G 8mm x 60cm; LMT-KATH-I 25G 12mm x 60cm; LMT-KATH-I 8mm x 60cm
Regulation Number: 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: December 11, 2006
Received: January 30, 2007

Dear Mr. Mushoff:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

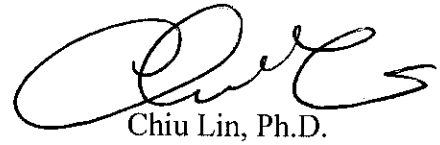
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Notification
Section D.
Statement of Indications for Use

Indications for Use Statement

510(k) Number: K062308

Device Name:
LMT-KATH-S 28G 10mm x 60cm
LMT-KATH-S 28G 8mm x 60cm
LMT-KATH-I 25G 12mm x 60cm
LMT-KATH-I 25G 8mm x 60cm

Indications for Use:
LMT-KATH-S 28G 10mm x 60cm
LMT-KATH-S 28G 8mm x 60cm
LMT-KATH-I 25G 12mm x 60cm
LMT-KATH-I 25G 8mm x 60cm
Infusion Sets are indicated for the infusion and/or injection of medication that is dispensed by means of micro-dosage pump into the body below the surface of the skin.

Prescription Use ____X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Richard C. Chapman for NDW 3/20/07

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

(Division Sign-Off) Number K062308